REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and the following commentary.

I. Status of the Claims

Claims 1 and 37 have been amended to recite that the active agent has an effective average particle size of greater than about 2 microns prior to inclusion in the dosage form. Claim 19 has been amended to recite that the active agent has an effective average particle size of less than about 2 microns prior to inclusion in the dosage form. Claim 25 has been amended to set forth the subject matter more clearly. Claims 38-57 have been added. Exemplary support for these amendments can be found in the original claims. Claim 18 is cancelled in view of the amendments to the claims.

Because no new matter is introduced, Applicants respectfully request entry of this amendment. Upon entry, claims 1-17, 19-26, 28-30, and 37-57 will be under examination, with claims 27 and 31-36 withdrawn.

II. Statement of Substance of Interview

Applicants confirm receipt of Examiner's voice mail left for Applicants' representative on October 22, 2007, that search for claim 26 will be concentrated on the pharmaceutical agents.

III. Rejection of Claims under 35 U.S.C. §102(b)

Claims 1-17, 25, 26 and 37 are rejected under 35 U.S.C. §102(b) for alleged anticipation by U.S. Patent No. 6,287,596 to Murakami *et al.* ("Murakami") or U.S. Patent No. 6,299,904 to Shimizu *et al.* ("Shimizu"). Claims 1, 4, 5, 7, 8-17, 25, 26 and 37 are rejected under 35 U.S.C. §102(b) for alleged anticipation by PCT Application Publication No. WO 00/50013 by Martyn *et al.* ("Martyn"). Applicants respectfully traverse each ground of the rejections.

Because the anticipation rejection does not include claim 18, claim 1 and claim 37 have been amended to incorporate the recitations of claim 18. Because none of the cited art has any teaching regarding the particle size of the active agent, the claimed invention is not anticipated by the cited art. Accordingly, withdrawal of the rejection under 35 U.S.C. §102(b) is warranted.

IV. Rejection of Claims under 35 U.S.C. §103(a)

Claims 1, 18-24 and 28-30 are rejected under 35 U.S.C. §103(a) for allegedly being obvious over Murakami. Applicants respectfully traverse the rejection.

Murakami is directed to rapidly disintegratable compression-molded materials containing (a) fillers and (b) erythritol. Abstract of Murakami. In particular, Murakami is directed to the observation that when a mixture of erythritol and an ingredient selected from among organic and inorganic excipients is tableted, a rapidly disintegratable compression-molded material is obtained, which exhibits rapid disintegration and dissolution when placed in the oral cavity or water and which is endowed with high strength that does not permit collapse thereof throughout the processes of manufacture process. Murakami at col. 4, lines 6-17. Murakami does not provide any teaching regarding the particle size of an active agent to be incorporated into a dosage form, but rather states that "[n]o particular limitation is imposed on the pharmaceutically active ingredients which may be used in the present invention, and they may be added in accordance with intended uses in the form of powder, crystals, oil, solutions, or in any other forms." Murakami at col. 5, lines 55-60.

Claim 1 recites a solid dosage form comprising, *inter alia*, at least one active agent having an effective average particle size of greater than about 2 microns prior to inclusion in the dosage form. Claim 19 is directed to a solid dosage form comprising, *inter alia*, at least one active agent having an effective average particle size of less than about 2 microns prior to inclusion in the dosage form. In contrast to the claimed invention, Murakami does not have any

disclosure regarding the particle size of the active agent. Rather, Murakami states that there is "no particular limitation" on the active agent present in the dosage form.

To bridge the gap between the claimed invention and the cited art, the Examiner simply states that "active agents are generally obtained in powder forms and the particles of the powder have sizes that meet the limitations of claims...," without citing any reference or providing any reasoning. This reasoning does not provide any motivation to one of skill in the art at the time the claimed invention was made to modify the teaching of Murakami to obtain the claimed invention.

To reject a claim based on an "Obvious to Try" standard – choosing from a finite number of identified, predictable solutions with a reasonable expectation of success, the Examination Guidelines for Determining Obviousness Under 35 U.S.C. §103 in view of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*, as published in the Federal Registrar/Vol. 72, No. 195/ Wednesday, October 10, 2007, require the Office Action to articulate the following:

(1) a finding that at the time of the invention, there had been a recognized problem or need in the art, which may include a design need or market pressure to solve a problem;

(2) a finding that there had been a finite number of identified, predictable potential solutions to the recognized need or problem;

(3) a finding that one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success; and

(4) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art.

The Guidelines require the Examiner to first resolve the Graham factual inquiries. According to the Guidelines, "[o]nce the findings of fact are articulated, Office personnel must provide an explanation to support an obviousness rejection under 35 U.S.C. §103. 35 U.S.C. §132 requires that the applicant be notified of the reasons for the rejection of the claim..." The Guidelines further state that "[t]he key to supporting any rejection under 35 U.S.C. §103 is the clear articulation of the reason(s) why the claimed invention would have been obvious."

The Examiner has failed to meet the initial burden to establish a *prima facie* case of obviousness, as a clear articulation of why one of skill in the art would select an active agent having a particle size of greater or less than about 2 microns, as required by the amended claims, particularly given that Murakami states that selection of the active agent form is not critical to the invention. As the claimed invention, as amended, is not obvious in view of the cited art, withdrawal of this ground for rejection is respectfully requested.

V. Rejection of Claims under 35 U.S.C. §112, second paragraph

Claim 13 is rejected under 35 U.S.C. §112, second paragraph, for allegedly being indefinite. Applicants respectfully traverse the rejection.

Claim 13 depends from claim 1, which is directed to a solid dosage form. The Examiner contends that the "aerosol formulation in claim 13 is unclear since fluids are not solids." Appended as Exhibit A is an online Wikipedia entry (printed January 10, 2008) for the term "aerosol," which explains that "[a]erosol technically refers to airborne liquid droplets or ***solid particles***...the term aerosol...now embraces both liquid droplets, ***solid particles***, and combinations of these" (emphasis added). Therefore, the recitation of claim 13 is consistent with that of the base claim. Applicants respectfully request withdrawal of the rejection.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 02/29/2008

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Exhibit A

Aerosol

From Wikipedia, the free encyclopedia

Aerosol technically refers to airborne liquid droplets or solid particles (also called dust or particulate matter (PM)). In casual language, **aerosol** refers to an aerosol spray can or the output of such a can.

The term **aerosol**, derives from the fact that matter "floating" in air is a suspension (a mixture in which solid or liquid or combined solid-liquid particles are suspended in a fluid). To differentiate suspensions from true solutions, the term **sol** evolved—originally meant to cover dispersions of tiny (sub-microscopic) particles in a liquid. With studies of dispersions in air, the term aerosol evolved and now embraces both liquid droplets, solid particles, and combinations of these. An aerosol may come from sources as various as a volcano or an aerosol can.

Contents

Workplace exposure

Concentrated aerosols from substances such as silica, asbestos, and diesel particulate matter are sometimes found in the workplace and have been shown to result in a number of diseases including silicosis and black lung.[1] The cooling effect of aerosols, however, does not seem to directly counteract the warming induced by greenhouse gases such as carbon dioxide, methane and water vapor and is accounted for in climate models, despite some claims that "global dimming" by aerosols may counteract global warming.[2]

References

1. ^ {{cite web|url= http://www.cdc.gov/niosh/topics/aerosols/default.html |title=NIOSH Aerosols Page|accessdate=2007-10-03|publisher=United States National Institute for Occupational Safety and Health} <ref> Respirators can protect workers from harmful aerosol exposure. The [[National Institute for Occupational Safety and Health] certifies respirators through the National Personal Protective Technology Laboratory to ensure that they protect workers and the public from harmful airborne contaminants.<ref>{cite web url= http://www.cdc.gov/niosh/npptl/ |title= NPPTL|accessdate=2007-10-03|publisher=United States National Institute for Occupational Safety and Health}<ref> == Effect on climate == [[Anthropogenic]] aerosols, particularly sulfate aerosols from [[fossil fuel]] combustion, exert a cooling influence on the climate.<ref>[http://www.grida.no/climate/ipcc_tar/wg1/figspm-3.htm IPCC TAR SPM figure 3] <li id="_note-1">'"[[#_ref-1|^]]"' {{cite web|url= http://www.realclimate.org/index.php/archives/2007/11/global-dimming-and-global-warming/ |title= RealClimate|accessdate=2007-11-27}} </ref>

See also

- Aerosol spray, the spraying device
- Bioaerosol
- Particulate, mixed-phase state of matter
- Pollution

External links

- National Institute for Occupational Safety and Health - Aerosols Page (http://www.cdc.gov/niosh/topics/aerosols/default.html)
- American Association for Aerosol Research (http://www.aaar.org/)

Retrieved from "http://en.wikipedia.org/wiki/Aerosol"

Categories: Physical chemistry | Occupational safety and health

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